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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,106	02/25/2004	Ming-Hui Wei	CL001180DIV	1623

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,106	WEI ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 24-38* is/are pending in the application.

4a) Of the above claim(s) *1,2,37 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 09/815,048.

Claims 4-23 have been canceled.

Claims 1-3 and 24-38 are currently pending and are the subject of examination in the present Office Action..

Election/Restrictions

1. Claims 1-2 and 37-38 stand as withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 18, 2006.

Accordingly, claims 3 and 24-36 are the subject of examination in the present Office Action.

2. In view of Applicant's amendment filed October 6, 2006 the following grounds of rejection are maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 3 and 24-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al (Biochem. Biophys. Res. Comm. [1995] 213(1):154-160; U on form PTO-892) in view of Campbell (Monoclonal Antibody Technology [1985] pages 1-32; V on form PTO-892).

It was previously stated: "Baker teaches the isolation and sequence of lanasterol synthase (see entire document, Figure 2 in particular). With respect to claim 3, the lanasterol synthase taught by Baker differs from instant SEQ ID NO: 2 only by the deletion of an 11 amino acid residue segment in the instantly disclosed SEQ ID NO: 2 versus the longer polypeptide taught by Baker, as evidenced by Figure 2c of the instant specification.

Baker does not teach making monoclonal antibodies to lanasterol synthase. With respect to claim 24, a sequence comprising SEQ ID NO: 2 encompasses the lanasterol synthase taught by Baker.

Campbell teaches that "[i]t is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (page 29, section "Basic research" in particular). It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make antibodies specific lanasterol synthase comprising the sequence of SEQ ID NO: 2. One would have been motivated, with a reasonable expectation of success, to generate mAbs to the peptides based on the fact that it is a conventional practice in the art to do so for further study, characterization and identification of a specific peptide and because of the role of lanasterol synthase in the biosynthesis of steroids as taught by Baker. While the lanasterol synthase protein taught by Baker is slightly longer than the instantly disclosed SEQ ID NO: 2, the artisan would reasonably expect that antibodies would be generated to epitopes distributed over the full length of lanasterol synthase and not just to the 11-amino acid segment of lanasterol synthase that is missing from SEQ ID NO: 2. There are no regions of instant SEQ ID NO: 2 that are not present in the lanasterol synthase protein taught by Baker."

Applicant's arguments filed October 6, 2006 have been fully considered but they are not persuasive. Applicant has amended claims 24 and 36 to recite "contiguous amino acid sequence of SEQ ID NO: 2" in an attempt to differentiate the claimed invention from the combination of the prior art references. Applicant argues that antibodies made to the protein of Baker would not necessarily bind to the instant SEQ ID NO: 2, because the instant polypeptide is 11 amino acid residues shorter than the 732 amino acid protein of Baker. Applicant argues:

> "one of skill in the art who designed an antibody to the protein of Baker et al. may very well design an antibody that binds wholly or partially to the extra 11 amino acid segment of the protein of Baker ct al., and such an antibody would not cross-match and bind with a protein of instant SEQ ID NO:2. It would not be obvious to limit the epitope to which the antibody binds to a region only within the 721 amino that correspond to instant SEQ ID NO:2"

Applicant's argument is not convincing. First of all, there is no teaching in Baker that would teach the artisan to specifically make antibodies to the 11 amino acid segment that is not present in the instant SEQ ID NO: 2. Furthermore, the artisan would not expect that raising antibodies to a 732 amino acid protein would result in antibodies that bind only to a single 11 amino acid segment of that protein, to the exclusion of producing antibodies to all other epitopes of the protein. Except for antibodies that bind to that particular 11 amino acid residues segment of the protein of Baker, antibodies to any epitope of the protein of Baker will specifically bind to the identical epitopes on instant SEQ ID NO: 2. there is no

limitation in the claims that the claimed antibody binds to any epitope of SEQ ID NO: 2 that is unique from the protein of Baker.

4. Claims 3 and 24-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al (Biochem. Biophys. Res. Comm. [1995] 213(1):154-160; U on form PTO-892) in view of Campbell (Monoclonal Antibody Technology [1985] pages 1-32; V on form PTO-892) and Harlow et al. (Antibodies: A Laboratory Manual. [1988] pages 72-77, 92-97, 128-135, 141-157 and 628-631; W on form PTO-892).

It was previously stated: "Baker and Campbell have been discussed supra.
The combined references do not teach antibody fragments.
Harlow teaches that any substance which can elicit a humoral response can be used to prepare mAbs and that mAbs are powerful reagents for the testing for the presence of a desired epitope. Harlow teaches methods for immunizing animals for the production of polyclonal and monoclonal antibodies (pages 72-77, 92-97, 128-135 and 141-157 in particular) as well as the types of antigens to which such antibodies can be made including proteins, peptides, and carbohydrates (any of which could qualify as a ligand, depending on the receptor)(pages 153-154 in particular). Harlow further teaches that because antibodies may recognize small determinants they may be cross-reactive with similar epitopes on other molecules (page 24, last paragraph in particular) and that epitopes may be formed by linear epitopes within an amino acid sequence or to epitopes which are formed by determinants from different parts of a molecule which are brought together due to conformation of said molecule (page 25, first section in particular). Harlow further teaches the manufacture of Fab and $F(ab')_2$ fragments of monoclonal antibodies (pages 628-631 in particular). harlow also teaches the conventional practice of labeling antibodies (pages 321-323 in particular).
It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine these references to produce monoclonal antibodies to the NTPPH protein taught by Cardenal. One would have been motivated, with a reasonable expectation of success, to combine these references in order to generate monoclonal antibodies to NTPPH to assist in the identification of regions of the protein involved in the enzyme activity of NTPPH by Harlow's teaching that hybridomas which produce mAbs provide a limitless supply of antibodies which is desirable because even large supplies of antisera (polyclonal) will eventually run out (pages 141-142, section titled "Monoclonal antibodies are powerful immunochemical tools").
Claims 31-34 are included because any conventional diluent, such as water, physiological saline or PBS, would constitute such a "carrier" irrespective of the intended use."

Applicant provides no further argument regarding the applicability of the teachings of Harlow other than to state that the teachings of Harlow fail to correct the previously asserted deficiencies of the Baker and Campbell references. The alleged deficiencies of Baker and Campbell have been discussed supra. Accordingly this ground stands without further comment.

Conclusion

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 26, 2006

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PRIMARY EXAMINER
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